

CLINICAL SCIENCE

Vaginal cone use in passive and active phases in patients with stress urinary incontinence

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OBJECTIVE: To evaluate vaginal cone therapy in two phases, passive and active, in women with stress urinary incontinence.

METHODS: A prospective study was conducted at the Department of Obstetrics and Gynecology, São Paulo University, Brazil. Twenty-four women with a clinical and urodynamic diagnosis of stress urinary incontinence were treated with vaginal cones in a passive phase (without voluntary contractions of the pelvic floor) and an active phase (with voluntary contractions), each of which lasted three months. Clinical complaints, a functional evaluation of the pelvic floor, a pad test, and bladder neck mobility were analyzed before and after each phase.

RESULTS: Twenty-one patients completed the treatment. The reduction in absolute risk with the pad test was 0.38 ($p < 0.034$) at the end of the passive phase and 0.67 ($p < 0.0001$) at the end of the active phase. The reduction in absolute risk with the pelvic floor evaluation was 0.62 ($p < 0.0001$) at the end of the passive phase and 0.77 ($p < 0.0001$) at the end of the active phase. The reduction in absolute risk of bladder neck mobility was 0.38 ($p < 0.0089$) at the end of the passive phase and 0.52 ($p < 0.0005$) at the end of the active phase. Complete reversal of symptomatology was observed in 12 (57.1%) patients, and satisfaction was expressed by 19 (90.4%).

CONCLUSION: Using vaginal cones in the passive phase, as other researchers did, was effective. Inclusion of the active phase led to additional improvement in all of the study parameters evaluated in women with stress urinary incontinence. Randomized studies are needed, however, to confirm these results.

KEYWORDS: Urinary Incontinence; Physical Therapy; Ultrasonography; Pelvic Floor; Muscle Dysfunction.

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INTRODUCTION

Stress urinary incontinence (SUI) is defined as the involuntary leakage of urine during effort.¹ It produces serious social and psychological problems that have a significant impact on a woman's health.¹

Normally, the bladder and urethra are supported by endopelvic fascia as well as by ligamentous and pelvic floor muscles.² Descent of the bladder and urethra has been observed in women with SUI, and this hypermobility may result from denervation of the levator ani muscle.² Thus, pelvic floor musculature, composed of both type I (slow) and type II (fast) muscle fibers, is important in the urinary continence mechanism.³

Several treatment options are available for managing SUI. Techniques aimed at strengthening the pelvic floor muscles

are often considered the first-choice treatment because of their noninvasive character, the possibility of combining them with other treatments, the low risk of side effects and the moderate-to-low costs.⁴ According to a review by Cochrane, pelvic floor muscle exercises must be included in the first line of conservative management programs for women with SUI.⁵

The first technique was described in 1948 by Kegel,⁶ who prescribed rapid voluntary contractions of the pelvic floor muscles. The author observed that 70% of the patients improved or were cured. However, even when provided with information on the anatomy and function of these muscles, 30% of the patients were unable to perform adequate voluntary contraction, instead eliciting contraction of the rectus-abdominal, thigh adductor, or gluteus maximus muscles—some patients performed the Valsalva maneuver.⁷

The use of vaginal cones to strengthen pelvic floor muscles was initially proposed by Plevnik in 1985.⁸ The patients were instructed to walk for 15 minutes twice a day with a cone in the vagina, without making a voluntary contraction despite the sensation of losing the cone. This

sensation, however, produced an involuntary contraction of the pelvic floor musculature, as shown by electromyography of the pelvic floor during the use of a vaginal cone.⁹

In a study with rats, analysis of the functional and histological effects of intravaginal electrical stimulation¹⁰ revealed that 5-second contractions increased type II fibers but not type I fibers.

In terms of the SUI treatment, some authors were equally successful with both the vaginal cone therapy recommended by Plevnik, which involves slow fibers, and with the pelvic floor muscle exercises, which involve fast fibers.¹¹

Thus, we wanted to evaluate the utilization of vaginal cones in associated passive and active phases; such use might produce an additional recruitment of type I and II fibers in the pelvic floor.

METHODS AND MATERIALS

Twenty-four women with SUI, according to clinical and urodynamic evaluations, were consecutively selected for study at the Gynecology Division, Department of Obstetrics and Gynecology, São Paulo University Medical School. This study was approved by the Internal Review Board of the institution and all patients signed an informed consent form prior to the study. The mean age of the patients was 34 years (28–40). Nineteen women were multiparous, with at least two vaginal deliveries each; three reported only one vaginal delivery; one had undergone two cesarean sections; and one was nulliparous. The average number of vaginal deliveries per patient was 2.3. All patients were white, and the body mass index (BMI) mean was 25.5 kg (mean weight, 66 kg).

The diagnosis of SUI was based on clinical history, a urogynecological examination, and a urodynamic evaluation. During the urogynecological examination, the patients were assessed and classified according to the pelvic organ prolapse quantification (POPQ):¹² 17 patients were in stage II, while 7 were in stage I.

The exclusion criteria comprised surgical treatment for SUI, clinical treatment for SUI in the 6 months prior to the study, use of medication affecting the lower urinary tract, inability to contract the pelvic floor muscles voluntarily, inability to keep cone number 1 (the lightest) in the vagina, pregnancy, menopause, diabetes mellitus, chronic pulmonary obstructive disease, genital prolapse stage III or IV,¹² neurological abnormalities of the perineal region, cervical infection, urinary tract infection, pelvic tumors, overactive bladder, or intrinsic sphincteric deficiency.

Vaginal cones are stainless steel devices with a plastic coating and a nylon thread at their apex to facilitate their removal. A set of 5 cones (figure 1) of similar shape and volume was used, numbered from 1 to 5 and weighing 20.0,

32.5, 45.0, 57.5, and 70.0 grams, respectively (Femtone®, Bristol Myers Squibb, Brazil).

Prior to the treatment, the patients were taught how to contract their pelvic floor muscles correctly. The treatment consisted of two 3-month phases. The first was the passive phase, and the second, the active phase. In the passive phase, as recommended by the majority of authors,² while in a standing position, the patient introduced the heaviest cone she could keep in her vagina with the apex pointing toward the pelvic floor. The sensation of losing the cone produced involuntary contractions of the pelvic floor musculature. The patient initially introduced cone number 1; if she did not feel the sensation that it was slipping out, cone number 2 was then inserted; the replacements continued with consecutively heavier weights until a sensation of loss was perceived. The patient was then instructed to walk and not to contract her pelvic floor musculature for one minute and to report any sensation of losing the device. We thus identified the initial “passive cone.”

The subject was instructed to walk for 15 minutes twice a day with the passive cone in her vagina without voluntarily contracting her pelvic floor muscles. When the patient no longer felt the cone was falling from her vagina, the next heaviest cone was used. This procedure was continued for three months.

The active phase was initially performed with the heaviest cone the patient was able to retain in the vagina in a standing position for one minute via voluntary contraction of the pelvic floor muscles. To find the correct cone, the patient started by introducing the next heaviest device used at the end of the passive phase. If she was able to retain it in the vagina easily, she tried to use the next heaviest cone. Replacements continued until the cone fell from the vagina, in which case, the subject would begin the active phase with the previous cone. If the patient ended the passive phase with cone number 5, she would start the active phase with the same number device.

After identifying the “active cone,” the patient was instructed to perform 30 voluntary contractions of 5 seconds each, alternating with 5 seconds of relaxation, twice a day, in a standing position. When she was able to retain the cone easily, the next heaviest device was used. The patients were evaluated once a week by the author, and he determined whether they were using the vaginal cones correctly.

Three patients abandoned the study after completing the passive phase and were excluded from the study. One moved from the city, and the other two preferred to seek surgical treatment.

Clinical and ultrasonographic evaluations were performed before and after each of the two phases. The clinical

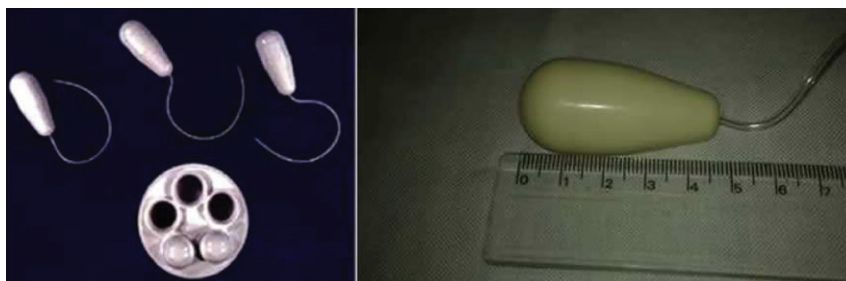


Figure 1 - Vaginal cones.

assessment consisted of an analysis of clinical complaints, a functional pelvic floor evaluation, and a pad test. Ultrasound was used to estimate bladder neck mobility and thus to indirectly evaluate pelvic floor muscle strengthening.²

The severity of incontinence was subjectively determined through the patient's report of her clinical response to the treatment and her satisfaction with it.

For analytical purposes, the patients were divided in four groups as follows: a) unchanged; b) improved but unsatisfied with the treatment; c) improved and satisfied with the treatment; d) completely dry. Satisfaction with the treatment meant the patient did not want another treatment option; therefore, she was analyzed only at the end of the study.¹³

Pelvic floor muscle function was evaluated according to the grading system proposed by Ortiz et al., 1994. The patients were put into the gynecological position and instructed to contract the pelvic floor muscles for five seconds. The following scores were used to report the results of this procedure:¹⁴

- 0: Neither visual sign nor digital perception of vaginal muscle contraction
- 1: No visual sign of muscle contraction, but perception of a weak contraction upon vaginal palpation
- 2: Weak muscle contraction upon both visual survey and vaginal palpation
- 3: Good muscle contraction at both visual survey and vaginal palpation but with no resistance to palpation
- 4: Strong muscle contraction at both visual survey and vaginal palpation but with less than 5 seconds of resistance to palpation
- 5: Strong muscle contraction at both visual survey and vaginal palpation with 5 seconds of resistance to palpation

Musculature was considered weak if the score of the functional pelvic floor evaluation was less than 3.¹⁵ Urine loss was evaluated using the 1-hour pad test with a standardized bladder volume^{13,16} when 250 ml were introduced by catheter into the bladder. Pad weights were measured in grams, and a weight of less than 2 g was considered normal.^{13,16,17}

Bladder neck mobility was assessed by introital ultrasound with the patient in a standing position and with an intravesical volume of 200 to 250 ml, as defined by transabdominal ultrasonography (Sonochrome, General Electric) using a 5 MHZ vaginal transducer. The distance between the bladder neck and the pubic symphysis was measured at rest and during stress maneuvers (Valsalva). Measurements were made according to an orthogonal system of Cartesian coordinates, using the inferior limit of the pubis symphysis as the point of origin. Bladder neck mobility from rest to stress was measured in millimeters. Less than 10 mm of bladder neck mobility was considered normal.¹⁸

In the statistical analysis, Pearson's chi-square test, Fisher's exact test and Student's t-test were used to analyze the pad test, the bladder neck mobility, and the functional pelvic floor evaluation at the end of each of the two phases. $P < 0.05\%$ was considered statistically significant. An intention-to-treat analysis was also performed.

RESULTS

The results showed that 21 (87.5%) patients completed the treatment. Three women (13.5%) withdrew from the study: one moved from the city and the other two requested surgical treatment (figure 2).

The absolute risk of the pad test (>2 g) at baseline was 1. At the end of the passive phase, the reduction in absolute risk was 0.38 ($p = 0.0034$); at the end of the active phase, this value was 0.67 ($p < 0.0001$) (table 1). In the intention-to-treat analysis (24 patients), the absolute risk at baseline was 1 (>2 g), while the reduction in absolute risk at the end of the passive phase was 0.33 ($p = 0.0039$); at the end of the active phase, this value was 0.58 ($p < 0.0001$) (table 2). When comparing the variation in mean values between the passive phase endpoint and the baseline (16.11 g) with that between the active phase endpoint and the baseline (18.39 g), the difference was 2.28 g ($p = 0.61$) (table 3).

The absolute risk of the functional evaluation of the pelvic floor (≤ 3) at baseline was 0.81. At the end of the passive phase, the reduction in absolute risk was 0.62 ($p < 0.0001$); at the end of the active phase, this value was 0.77 ($p < 0.0001$) (table 1). In the intention-to-treat analysis (24 patients), the absolute risk at baseline was 0.83 (≤ 3), while the reduction in absolute risk at the end of the passive phase was 0.65 ($p = 0.0004$); at the end of the active phase, this value was 0.66 ($p < 0.0001$) (table 2). When comparing the variation in mean values between the passive-phase endpoint and the baseline (1.09) with that between the active-phase endpoint and the baseline (1.61), the difference was 0.52 ($p = 0.01$) (table 3).

The absolute risk of bladder neck mobility (>10 mm) at the baseline was 0.95. At the end of the passive phase, the reduction in absolute risk was 0.38 ($p = 0.0089$) (table 1); at the end of the active phase, this value was 0.52 ($p = 0.0005$). In the intention-to-treat analysis (24 patients), the absolute risk at baseline was 0.95 (>10 mm), while the reduction in absolute risk at the end of the passive phase was 0.33 ($p = 0.01$) and 0.45 ($p = 0.0007$) at the end of the active phase (table 2). Comparing the variation in mean values between the passive-phase endpoint and the baseline (4.80 mm) with that between the active-phase endpoint and the baseline (6.55 mm), the difference was 1.75 mm ($p = 0.12$) (table 3).

With respect to the clinical questionnaire, 12 (57.1%) patients reported complete recovery; 7 (33.3%) reported improvement and satisfaction; and 1 (4.8%) reported no change. Thus, 19 (90.4%) patients were satisfied with the treatment, and 10 (47.6%) patients, who showed improvement at the end of the passive phase, were found to be cured at the end of the active phase (table 4). These results were statistically significant ($p = 0.0002$).

DISCUSSION

There are many available treatment options for SUI. The techniques aiming at strengthening pelvic floor muscles lead to reduction in muscle dysfunction, one of the main causes of SUI.²

Nevertheless, 30% of the patients are unable to perform an adequate voluntary contraction.⁷ The use of vaginal cones elicits a specific, effective muscle contraction because the patient needs to contract the pelvic floor muscles^{2,8,15} while concomitantly decreasing accessory muscle contractions in order to retain the cone in the vagina.

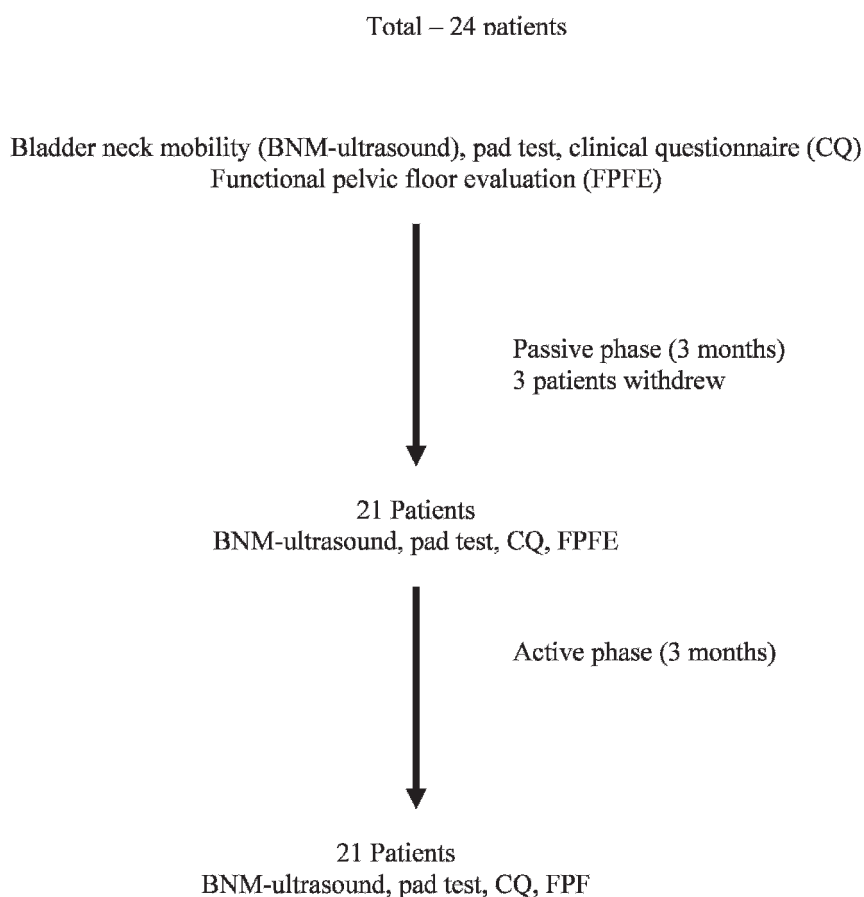


Figure 2 - Overview of patients during the treatment.

Table 1 - Analysis of the pad test, the bladder neck mobility, and the functional pelvic floor evaluation at baseline and at the end of the passive and active phases.

| | N | Outcome before treatment (N) | AR of outcome before treatment | Outcome after passive phase (N) | AR of outcome after passive phase | RAR of outcome after passive phase | NNT of passive treatment | Outcome after active phase (N) | AR of outcome after active phase | RAR of outcome after active phase | NNT of active treatment |
|------------------------------------|---|------------------------------|--------------------------------|---------------------------------|-----------------------------------|-------------------------------------|--------------------------|--------------------------------|----------------------------------|-------------------------------------|-------------------------|
| Pad test | 3 | 7 | 0.33 | 0.67 | 1 | (outcome ≥ 2 g) | 21 | 21 | 1.0 | 13 | 0.62 |
| | | | | | | IC 95% 0.17 – 0.58 P = 0.0034 | IC 95% 2 - 6 | | | IC 95% 0.46 – 0.86 P < 0.0001 | IC 95% 1 - 2 |
| Bladder neck | 3 | 9 | 0.42 | 0.52 | 2 | (outcome ≥ 10 mm) | 21 | 20 | 0.95 | 12 | 0.57 |
| | | | | | | IC 95% 0.15 – 0.61 P = 0.0089 | IC 95% 2 - 7 | | | IC 95% 0.29 - 0.75 P = 0.0005 | IC 95% 1 - 3 |
| Functional pelvic floor evaluation | 2 | 1 | 0.04 | 0.77 | 2 | (outcome ≤ 3) | 21 | 17 | 0.81 | 4 | 0.19 |
| | | | | | | IC 95% 0.38 – 0.85 P < 0.0001 | IC 95% 1 - 3 | | | IC 95% 0.57 – 0.95 P < 0.0001 | IC 95% 1 - 2 |

N- number of patients; RAR: reduction in absolute risk.
AR: absolute risk NNT: necessary number to treat.

Table 2 - An intention-to-treat analysis of the pad test, the bladder neck mobility and the functional pelvic floor evaluation at baseline and at the end of the passive and active phases.

| | N | Outcome before treatment (N) | AR of outcome before treatment | Outcome after passive phase (N) | AR of outcome after passive phase | RAR of outcome after passive phase | NNT of passive treatment | Outcome after active phase (N) | AR of outcome after active phase | RAR of outcome after active phase | NNT of active treatment |
|--|----|------------------------------|--------------------------------|---------------------------------|-----------------------------------|---|--------------------------|--------------------------------|----------------------------------|---|-------------------------|
| Pad test (outcome ≥ 2 g) | 24 | 24 | 1.0 | 16 | 0.66 | 0.33 IC 95% 0.14 – 0.52 P = 0.0039 | 3 IC 95% 1 - 3 | 10 | 0.41 | 0.58 IC 95% 0.38 – 0.78 P < 0.0001 | 2 IC 95% 1 - 3 |
| Bladder neck mobility (outcome ≥ 10 mm) | 24 | 23 | 0.95 | 15 | 0.62 | 0.33 IC 95% 0.12 – 0.54 P = 0.01 | 3 IC 95% 2 - 8 | 12 | 0.50 | 0.45 IC 95% 0.24 – 0.67 P = 0.0007 | 2 IC 95% 1 - 4 |
| Functional pelvic floor evaluation (outcome ≤ 3) | 24 | 20 | 0.83 | 7 | 0.29 | 0.65 IC 95% 0.37 – 0.93 P = 0.0004 | 2 IC 95% 1 - 3 | 4 | 0.16 | 0.66 IC 95% 0.45 – 0.87 P < 0.0001 | 2 IC 95% 1 - 2 |

N- number of patients; RAR: reduction in absolute risk.
AR: absolute risk; NNT: necessary number to treat.

The majority of authors recommend only passive use of this technique.^{8,15,19,20} In our study, cones were used in two different phases, passive and active, to stimulate the use of muscle fiber types I (slow) and II (fast). In the passive phase, type I fibers were stimulated when the contractions were prolonged.²¹ However, in the active phase and during the exercises proposed by Kegel,⁴ there was an increase in the use of type II fibers.^{11,22}

The duration of this therapy is controversial. It can last from one week to six months.^{2,13,23} To assess the real potential of a treatment that is aimed at improving muscle strength, the American College of Sports Medicine²⁴ recommends that therapy be continued for at least five months. In our study, we opted to extend treatment to six months.

There is no consensus as to the methods that may be used for subjective and objective evaluation of urine loss during

Table 3 - Comparison of the variation in the mean value of the passive-phase endpoint and baseline with that of the variation in the mean value of the active-phase endpoint and baseline: pad test, bladder neck mobility, and functional pelvic floor evaluation.

| PAD TEST | | |
|------------------------------------|-----------------------------|----------------------------|
| VARIATION | MEAN VALUE OF PASSIVE PHASE | MEAN VALUE OF ACTIVE PHASE |
| AVERAGE | 16.11 | 18.39 |
| STANDARD DEVIATION | 11.89 | 16.84 |
| N | 21 | 21 |
| Average reduction: 2.2800 | | |
| IC 95%: -11.3717 to 6.8117 | | |
| P = 0.61 | | |
| BLADDER NECK MOBILITY (Ultrasound) | | |
| VARIATION | MEAN VALUE OF PASSIVE PHASE | MEAN VALUE OF ACTIVE PHASE |
| AVERAGE | 4.80 | 6.55 |
| STANDARD DEVIATION | 3.49 | 3.72 |
| N | 21 | 21 |
| Average reduction: 1.75 | | |
| IC 95%: -3.9996 to 0.4996 | | |
| P = 0.1238 | | |
| FUNCTIONAL PELVIC FLOOR EVALUATION | | |
| VARIATION | MEAN VALUE OF PASSIVE PHASE | MEAN VALUE OF ACTIVE PHASE |
| AVERAGE | 1.0900 | 1.6100 |
| STANDARD DEVIATION | 0.7000 | 0.6600 |
| N | 21 | 21 |
| Average increase: 0.5200 | | |
| IC 95%: -0.9443 to -0.0957 | | |
| P = 0.01 | | |

Table 4 - Clinical questionnaire at the beginning and end of the passive and active phases.

| | Passive phase (%) | Active phase (%) |
|--------------------------|-------------------|------------------|
| Unchanged/ aggravated | 1 (4.8) | 1 (4.8) |
| Improved/unsatisfied | * | 1 (4.8) |
| Improved/satisfied | * | 7 (33.3) |
| Completely dry | 2 (9.6) | 12 (57.1) |

*Satisfaction was evaluated only at the end of the treatment.

SUI therapy.² In most reported studies, the subjective evaluation is based on a quality-of-life questionnaire^{2,12} with items about the severity of urine loss and with items requesting assessment of the patient's condition as satisfied or unsatisfied.¹³ In our sample, two patients were not satisfied and one was unchanged at the end of the treatment. This patient scored 0 in her pelvic floor evaluation and underwent surgery and a biopsy of the pelvic floor muscle, the result of which demonstrated that the type II fibers were completely degenerated. She was the only patient in whom pelvic floor function did not improve.

The results showed that 19 (90.4%) patients were satisfied with the treatment, and 10 (47.6%) patients, who showed improvement at the end of the passive phase, were found to be cured at the end of the active phase. These good results were probably obtained because of the addition of the active phase to this therapy, or rather, because of the complementary recruitment of type I and type II muscle fibers. Had the passive phase alone been used, as is done in a majority of the other studies, the results might not have shown such improvements.

Peattie et al.²⁰ reported a study in which 30 patients used vaginal cones in a passive phase for one month and afterwards performed the exercises recommended by Kegel⁶ for an additional month. Following the vaginal cone phase, 70% of the patients were found to be completely dry or to have improved with respect to urinary loss. No clinical improvement was reported in the second phase, probably because the patients did not practice the contractions correctly.

In our study, patients also reported a reduction in urinary loss in the active phase, increasing the percentage of completely dry patients from 8.3% at the end of the passive phase to 57.1% at the end of the treatment. Such a reduction probably occurred because the use of the cones stimulated adequate contraction of pelvic floor muscles and taught them to perform Kegel's exercises correctly. The patients were requested to incorporate these exercises into their daily routine in order to maintain the beneficial effect after the end of the study.²⁵

With reference to the objective evaluation of this therapy, most investigators recommend the pad test, as suggested by the International Continence Society (ICS).^{2,19,20} However, one may claim that improvement was possibly due to the variation in intravesical volume.²⁶ We chose to use the pad test indicated by the ICS, but we adopted an intravesical volume of 250 ml, which was perfectly well tolerated by the patients. We found a significant reduction in the absolute risk at the end of the passive and active phases, including in an intention-to-treat analysis, perhaps owing to the complementary recruitment of type I and II muscle fibers during muscular contraction of the pelvic floor.

Different methods have been described for evaluating the anatomic support of the bladder and urethra. In this study, introital ultrasound was used to analyze bladder neck mobility.¹⁸ Several authors showed that ultrasonography was a good tool for evaluating the nonsurgical treatment of patients with SUI.^{2,27} Those researchers reported a reduction in bladder neck mobility in patients using vaginal cones.²⁷

In our study, there was a significant decrease in absolute risk at the end of both the passive and active phases, including the intention to treat. The only patient whose symptoms were unchanged had 20.8 mm of bladder neck mobility at the end of the treatment.

A systematic review of studies on vaginal cone use for SUI treatment² showed that the authors reported a 21% dropout rate. In our study, however, only three patients discontinued treatment: one moved from the city and the other two requested surgical treatment. Weekly evaluation and analysis to check whether the vaginal cones were being used correctly may explain the discrepancy between the results of our study and those of the aforementioned authors.

Kondo et al.²⁸ observed that 10% of the patients using vaginal cones reported side effects such as vaginal pain and increased vaginal discharge; however, no treatment was required, and there was no need to discontinue therapy. No side effects were observed in our study.

In conclusion, using vaginal cones in the passive phase, as other researchers have done, was effective. Inclusion of the active phase induced additional improvement in all of the study parameters for women with stress urinary incontinence. Randomized studies are needed, however, to confirm these results.

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